DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 11, 2014

AngioDynamics Inc.
Wanda Carpinella
26 Forest Street
Marlborough, MA 01752

Re: K142607
Trade/Device Name: AngioVac Circuit
Regulation Number: 21 CFR 870.4390
Regulation Name: Cardiopulmonary bypass pump tubing
Regulatory Class: II
Product Code: DWE
Dated: September 11, 2014
Received: September 15, 2014

Dear Ms. Carpinella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram Zuckerman, MD
Director, Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142607

Device Name
AngioVac Circuit

Indications for Use *(Describe)*
The AngioVac Circuit is indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY (page 1 of 2)

Device Name: AngioVac Circuit **Date Prepared:** September 11, 2014

A. Submitter/Sponsor

AngioDynamics Inc.
26 Forest Street
Marlborough, MA 01752
Telephone Number/Fax: 508-658-7929/508-658-7976
Contact Person: Wanda Carpinella

B. Device Name

Trade Name:	AngioVac Circuit
Common/Usual names:	Cardiopulmonary Bypass Circuit
Classification Names:	Cardiopulmonary bypass pump tubing 21 CFR§870.4390 ProCode DWE
Classification:	Class II

C. Predicate Device(s)

Trade Name	510(k)	Company
Vortex Medical, Inc. AngioVac Cardiopulmonary Bypass Circuit	K092486	Vortex Medical Inc. (acquired by AngioDynamics Inc.)

D. Device Description

The AngioVac Circuit is an extracorporeal perfusion set that includes four subassemblies including a main perfusion circuit (manufactured of 0.375" non-DEHP PVC coextruded tubing with Y-connector, tubing quick-connects and priming line), waste line, tuohy adapter and reinfusion cannula connector. An extra reinfusion cannula connector and tuohy adapter are provided in a sealed pouch with the circuit.

E. Indications For Use

The AngioVac Circuit is indicated for use in procedures requiring extracorporeal circulatory support for periods of up to six hours.

F. Technology Characteristics

Within this current premarket notification, AngioDynamics is proposing to implement design modifications to the AngioVac Circuit. The changes proposed are designed to facilitate extracorporeal circuit set-up including improved connectors, longer tubing lengths and enhanced packaging presentation. There has been no change to the indications for use, nor do the proposed changes significantly affect the technological characteristics or principle of operation for the device as described in K092486. Included among the changes proposed, is that a male quick connector has been added to the blood drainage line of the circuit assembly. The male quick connector has been designed to specifically interface with a female quick connector to be provided on AngioDynamic's venous drainage cannula; i.e., the AngioVac Cannula (reference K133445). Due to this change, the circuit has been labeled with the statement that it is intended to be used solely with the AngioVac Cannula as the venous drainage cannula.

G. Performance Data

Bench testing, including physical integrity and performance testing, was performed to support substantial equivalence of the AngioVac Circuit The AngioVac Circuit met all specified design and performance requirements. Additionally, the AngioVac Circuit has fulfilled the biocompatibility testing requirements identified in ISO 10993: Biological evaluation of medical devices Part 1: Evaluation and testing in the risk management process. The product was evaluated as an externally communicating device, circulating blood path with a limited contact duration (≤ 24 hours). Testing performed included: Cytotoxicity, Intracutaneous Reactivity, Acute Systemic Toxicity, Guinea Pig Sensitization and Hemocompatibility. No adverse effects were noted in any tests performed.

H. Clinical Testing

Not applicable

I. Conclusion

Based on responses to questions posed in the FDA's Decision Making Flow Chart, the proposed device is substantially equivalent to the predicate device.